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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 10 1998

WARNING LETTER

Ref:OC:I1-1781

via FEDERAL EXPRESS

Mr. Paul Suni
President
LightWorks, LLC
8513 North 95th Street
Longmont, Colorado 80501

Dear Mr. Suni:

This letter is written to advise you of items of noncompliance with the Federal laser product performance standard encountered during a review of your laser product report, Accession No. 9810259, concerning the SpeedReader model family of laser based speed sensors. The following noncompliances were found.

1. 21 CFR 1040.10(c). Classification of laser products. You have failed to classify your products in accordance with the Federal laser product performance standard as specified in this paragraph and, by reference, paragraph (d). Products which must be certified under the Federal laser product performance standard, must be classified in accordance with the requirements of that standard.

   Please re-determine your product classification in accordance with 1040.10(c) and submit this re-determination in a supplement to your product report.

2. 21 CFR 1040.10(f), (g), and (h). Performance, Labeling, and Informational Requirements. Further, if the product when classified under the Federal laser standard is not Class I, then the product does not provide the applicable performance features and warning labeling as specified in 1040.10(f) and (g). If your product is not Class I, please include in your report supplement descriptions of how you will provide each applicable performance feature and each required label.

   Also the discussion of laser safety on page 2 of the User Manual for the SpeedReader 100 would have to be revised if the product is not Class I. Other revisions, as required by 1040.10(h)(1), would also be required in this case. But, if it is Class I, we recommend revising it to at least include the Federal laser standard classification in the safety discussion. Please include a copy of the revised User Manual in your report supplement.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

    b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, Denver District Office, Food and Drug Administration, P.O. Box 25087, 6th and Kipling Street, Denver, Colorado 80225. If you have further questions on these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spear for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health